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EXAMINER	
SCHMIDT, MARY M	
ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,932	FIRTH, GREG	
	Examin r	Art Unit	
	Mary M. Schmidt	1635	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10* is/are allowed.

6)☒ Claim(s) *11,12,14-16,21 and 27* is/are rejected.

7)☒ Claim(s) *11 and 17--26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

2. In the previous Official Actions mailed 08/27/01 and 05/28/02 acknowledgment was made of Applicants' claim for foreign priority based on an application filed as EPO 98/42867 on March 21, 1998, since the previous Oath and Declaration had listed EPO 98/42867 as a priority document. It is noted, however, that the new Oath and Declaration filed 12/02/02, no longer claims priority to EPO 98/42867, and thus a certified copy is not further needed. However, Applicant wrote on page 8 of the response filed 12/02/02, that "Applicant is in the process of retrieving a certified copy of the priority document. Upon receiving the certified copy, Applicant plan to submit it to the USPTO by supplemental amendment". This statement is confusing since the new Oath and Declaration no longer claims priority to EPO 98/42867.

Applicant is notified that should the decision be made to further request priority to EPO 98/42867 in future responses, a new Oath and Declaration will be required at that time properly claiming priority to EPO 98/42867. A certified copy would also be necessary at that point to meet the requirements of 35 U.S.C. 119(b). However, since EPO 98/42867 is no longer claimed in the Oath and Declaration as a priority document, it is no longer necessary for applicant to provide a certified copy of the document.

Claim Objections

3. Claims 11 and 21 as amended in the response filed 12/02/02 is objected to because of the following informalities:

Claim 11 has typographical errors on line 4, "misture of alleses" should read "mixture of alleles."

Claim 21 does not have a concluding period punctuation mark.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. Claims 11, 12, 14, 15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgante et al., WO 96/17082, for the same reasons of record as set forth in the previous Official Actions mailed 08/27/01, 2/14/01, 6/6/00 and 05/28/02.

Applicant's arguments filed 12/02/02 have been fully considered but they are not persuasive.

Claims 11 and 12 as amended are drawn to a mixture of one or more VNTR alleles and their flanking regions, said mixture consisting essentially of a representative mixture of alleles of a chosen variable number tandem repeat (VNTR) sequence and their flanking regions on both sides, wherein each member of the representative mixture of alleles has an adaptor at each of its

3'-end and its 5'-end; wherein the mixture of alleles is representative of those which manifest a trait of interest.

Morgante et al. taught in Figure 11, and on page 18, lines 4-7, generation of genomic restriction fragments carrying an allelic repeat bordered at both ends by restriction site-specific adaptors, Ad_A and Ad_B. They thus taught the claimed mixture of VNTR alleles and their flanking regions (their alleles they called SSR regions, or "simple sequence repeat", see page 18, line 29) where the flanking regions have 3' and 5' adaptors. They taught wherein the SSR (VNTR) regions manifest a trait of interest on page 19, lines 3-5: "Simple sequence repeats are common in virtually all eukaryotic genomes studied and have been identified as useful tools for the study of genetic polymorphisms."

Claim 14 as amended is drawn to a composition consisting essentially of one or more copies of a single variable number tandem repeat (VNTR) allele and its flanking regions and an adaptor at each of its 3'-end and its 5'-end, said allele being characteristic of those which manifest a trait of interest.

As described above, Morgante et al. taught the a mixture, thus a composition of one or more copies of SSR (ie. VNTR) alleles having adaptor flanking regions at both the 5' and 3' end.

Claim 15 as amended is drawn to a mixture of VNTR flanking sequences, said mixture consisting essentially of a representative mixture of 3'-flanking regions of a chosen variable number tandem repeat (VNTR) sequence, each member of the mixture carrying an adaptor at its

3'-end, and a representative mixture of 5'-flanking regions of a chosen VNTR sequence, each member of the mixture carrying the same adaptor at its 5'-end.

As described above, Morgante et al. taught the a mixture of one or more copies of SSR (ie. VNTR) alleles having adaptor flanking regions at both the 5' and 3' end. According to figure 11 of Morgante et al., the original mixture of adaptor ligated restriction fragments all had an Ad_A on the 5' end and Ad_B on the 3' end.

Claim 21 is newly rejected by Morgante et al. since the method comprises dividing genomic DNA of one or more members of a species of interest into fragments and ligating to each end of each fragment an adaptor thereby forming a mixture of adaptor-terminated fragments in which each 3'-end is blocked to prevent enzymatic chain extension (instant steps a) and b)), but only one of either of steps c) or d) is required by the claim 21. Since Morgante et al. teaches in figure 11 (and page 18, lines 4-7) instant steps a) and b), the formation of fragments having 5' and 3' adaptors, and further teaches in figure 11, the first composition, the PCR of the AdB and SSR region, which results in the mixture of instant step c), of 5'-flanking VNTR amplimers.

Applicant states on page 12 of the response filed 12/02/02, that "The method of Morgante fragments the genomic DNA and ligates site specific adaptors to each end. However, because most of the fragments do not contain an SSR, such SSR-containing fragments with adaptors at both ends are only a minor portion within the mixture. Thus, Morgante does not disclose a mixture of one or more VNTR alleles and their flanking regions wherein the mixture consists

essentially of a representative mixture of alleles of a chosen VNTR sequence and their flanking regions on both sides...."

In response, it is unclear where applicant derives the assertion that "most" of the genomic fragments taught by Morgante do not contain an SSR. Morgante teaches generation of the genomic fragments via restriction enzyme digestion, the same method used by applicant in the instant disclosure on page 15, lines 3-8: "The use of one or more restriction enzymes gives rise to uniform fragmentation of the genomic sample and constitutes the preferred technique. With judicious choice of restriction enzymes that cut frequently there is potential for generation en masse of every VNTR of the chosen type within a genome or pool of genomes since virtually all fragments will be sufficiently small for efficient amplification." Thus, the fragments of Morgante et al., generated via restriction enzyme (page 18, lines 4-7 of Morgante et al.), overlap in scope, and consist essentially of the fragments instantly claimed and disclosed since the instantly claimed fragments were also generated via enzymatic restriction digestion as "the preferred technique." (Instant specification page 15, lines 4-5)

Applicant further points to an error in Figure 11 of Morgante et al., in the third construct down. However, this error does not affect the anticipation of the instantly claimed invention by Morgante et al. since the instant claims embrace the first construct in Figure 11 of Morgante, and not the third construct.

5. Claims 16 and 27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. for the same reasons of record as set forth in the Official Action mailed 08/27/01, 02/14/01 and 6/6/00 and 05/28/02.

Applicant's arguments filed 12/02/02 have been fully considered but they are not persuasive.

Applicant traverses the rejection on page 13 of the response filed 12/02/02. Applicants state that "[r]egarding claim 16, the nucleic acids being treated in Nelson are digested genomic DNA, which do not consist essentially of a mixture of polymorphic alleles representative of those which manifest a trait of interest. Indeed, any VNTR allele would be an extremely minor portion of the fragmented genomic DNA. Thus, Nelson does not anticipate claim 16."

In response, claim 16 states that the methods of treating nucleic acids which consist essentially of a mixture of polymorphic alleles are of "a mixture being representative of those which manifest a trait of interest." Thus, while it appears that applicant is interpreting the claim to the extent that the mixture of a trait of interest is limited to one VNTR allele trait of interest, the claim is drawn to use of a mixture of more than one polymorphic allele that is representative of "those which manifest a trait of interest." As such the teachings of Nelson et al. which start with a fragmented genomic population, provide use of a mixture of polymorphic alleles generated the same way as those instantly disclosed, ie. by restriction digestion of the genomic population. Claim 27 stands rejected for its dependency on claim 16.

Allowable Subject Matter

6. Claims 1-10 are allowed.

7. Claims 1-10 are considered free of the prior art since the closest prior art cited above did not teach the methods of using primers for amplifying VNTR alleles from genomic populations as claimed in the method steps of claims 1-10 and 21. The closest prior art is Morgante et al., but since Morgante et al. Teaches PCR with an SSR primer and an adaptor, followed by sequencing the product and design of an isfp-1 internal primer for making the pool of SSR containing fragments, they do not anticipate the limitations of instant claim 1, which are drawn to making the pool of fragments with the adaptor primers and the VNTR primers, the result of which would not be achieved by the method of Morgante et al.

8. Claims 17-20 and 22-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 17-20 and 22-26 are free of the prior art since the closest prior art, Nelson et al. applied to claim 16 above, is not considered to teach nor fairly suggest the limitations of instant claims 17-20 and 22-26. Claims 17-20, 23, 25 and 26 are considered free of the prior art since Nelson et al. did not specifically teach identification of a VNTR allele from the population of identity-by-descent fragments generated in their GMS procedure. Claims 22 and 24 are

considered free of the prior art since Nelson et al. did not teach nor fairly suggest hybridization of two different populations of polymorphic alleles and their flanking sequences wherein one of the populations contains polymorphic alleles known to contain a trait of interest, and wherein the second population of polymorphic alleles does not contain polymorphic alleles that manifest the trait of interest.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
February 23, 2003

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